DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

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February 20, 2002

VIA FEDERAL EXPRESS

Luc Chaltin
President
Newton Laboratories, Inc.
2360 Rockaway Industrial Blvd.
Conyers, Georgia 30012

WARNING LETTER
(02-ATL-21)

Dear Mr. Chaltin:

This letter is in reference to the marketing and distribution of "NEWTON RX BIO-PROTECT" by your firm. During an inspection of your facility on November 29 and December 6, 2001, FDA investigator, Myla D. Chapman, determined that you are manufacturing and distributing this product in liquid and pellet form. "BIO-PROTECT" is being promoted for conditions that cause it to be a drug as defined in Section 201(g)(1)(B) and 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act) and a biologic, as defined in Section 351(i) of the Public Health Service (PHS) Act.

The "BIO-PROTECT" label states that the product is "To assist with elimination of biological toxins and to help with symptoms such as high fever, flu like symptoms and vomiting". The promotional flyer sent to your customers about this product entitled "CALM AGAINST BIO-TERRORISM" states that "BIO-PROTECT is now available from the NEWTON RX line ***. Due to the fear inspired by the recent terrorist attacks against the U.S., most incoming calls have been asking us about homeopathic solutions to biological or chemical warfare". The flyer further states that the product contains "nosodes for most of the listed potential biological warfare agents including Anthracinum, Botulism, Yersinia pestis, Variolinum, Tularemia, Cholera, Yellow Fever, and Typhodinum ... In order to assist with an appropriate immune response and relieve potential symptoms, we have included Bryonia, Lycopodium, Phosphorus, China off., and Rhus tox. ..." This product is also promoted on a Bioterrorism link on your web site at the Internet address: http://www.newtonlabs.net.

In order to introduce or deliver for introduction such products into interstate commerce a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, biological products may be distributed for clinical use in humans only if the sponsor has on file an accepted investigational new drug application as specified by the regulations, Title 21, Code of Federal Regulations (21 CFR), Part 312. Exemptions from the requirements of demonstrated safety and efficacy for drug products are granted under Section 505 of the Act.

Based on a review of our files, FDA has no information that your product is the subject of an approved biologics license application (BLA) or an investigational new drug application (IND). Additionally, there is no information that your product is generally recognized as safe and effective for its intended use. Therefore, your shipments of product for which a valid license or IND is not in effect and which are at variance with the provisions of 21 CFR Part 312, are in violation of the PHS Act and Section 505(a) of the Act. In addition, these products are also misbranded (Section 502(f)(1) of the Act) because they do not bear adequate directions for use for the indications noted above.

The violations cited in this letter are not intended to be a statement of all the violations that may exist for products marketed by your firm. It is your responsibility to assure that all your products are in compliance with federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering contract awards. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

Within fifteen (15) working days of your receipt of this letter, please notify this office in writing of the specific steps you will take to correct the noted violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should include your plans as to the continued promotion and distribution of this product. In addition, you should discuss the proposed disposition of product still under your control.

Your reply should be sent to the Food and Drug Administration at the above letterhead address to the attention of Philip S. Campbell, Compliance Officer.

Sincerely,

Ballard H. Graham, Director
Atlanta District